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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,891	09/30/2003	Vaclav O. Podany	16334Z (ETH-5075CIP)	6130
23389 7590 09/19/2007 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER PEFFLEY, MICHAEL F	
			ART UNIT 3739	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/675,891

Applicant(s)

PODANY ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/30/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/1/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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Applicant's amendments and comments, received July 26, 2007, have been fully considered by the examiner. The amendments have obviated the 35 USC 101 and 35 USC 112 rejections. It is noted that claims 17-19 remain withdrawn from consideration. The following is a complete response to the July 26, 2007 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The oath/declaration filed January 14, 2004 states that applicant acknowledges the duty to disclose information material to the "examination" as defined in 37 CFR 1.56(a). The term "examination" should be replaced with "patentability" and 37 CFR 1.56(a) should be replaced with "37 CFR 1.56" as stated in the above form paragraph.

Drawings

The drawings filed September 30, 2002 appear to be informal. Formal drawings are required in response to this Office action. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Failure to timely submit replacement drawing sheets will result in
ABANDONMENT of the application.

Claim Rejections - 35 USC § 103

Claims 1-5, 7, 8 and 11-16 are rejected under 35 U.S.C. 103(a) as being
unpatentable over Phan (6,932,816) in view of the teaching of Stern et al (5,277,201).

Phan discloses a device comprising first and second support members (22,24)
each having a compliant material (156) coupled to the support member. Column 12,
lines 24+ disclose the compliant material as being inflated by a fluid, and lines 62-65
specifically state that the compliant material will conform to tissue when fluid is
provided. Each compliant member includes a lumen for providing a fluid to the
compliant member (160) and a return lumen (162), and there is an electrode member
(108) located in the compliant member for delivering RF energy to tissue. Phan fails to
specifically disclose an electrode located on the outer surface of the compliant member.

Stern et al discloses an RF balloon apparatus for providing RF energy to tissue.
In particular, Stern et al teach that RF energy may be provided to the tissue by
electrodes located on the surface of the balloon member or in the balloon member (col.
5, lines 47-59). Stern et al also teach that the electrodes may be provided by
impregnating the balloon outer surface with a metal (col. 5, lines 44-46), and that the
balloon may be porous for delivering an electroconductive fluid or gel (col. 5, lines 40-
45).

The examiner maintains that to have provided the Phan compliant material with
the electrode on the outer surface would have been an obvious alternative design

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consideration to allow for the delivery of RF energy to tissue, particularly since Stern et al teach that RF electrodes may be provided either within or on the outer surface of an inflatable RF delivery device.

Response to Arguments

Applicant's arguments filed July 26, 2007 have been fully considered but they are not persuasive.

Applicant asserts that Phan et al teach away from an electrode on the surface since the inflatable member is porous to allow the electroconductive fluid to pass through the balloon, and since a cooling fluid path is provided through the transmission space. Applicant further asserts that it is necessary and indispensable to provide an outer casing covering the electrode. The examiner disagrees. The use of balloons having RF electrodes and conductive fluid for delivering RF energy to tissue is very well known and established in the art. The examiner agrees that there are numerous references which provide an electrode within a balloon member with the advantage that the metal electrode does not need to contact tissue. This is clearly taught by Phan et al. However, it is not a "necessary and indispensable" feature in such a device that this relationship between electrode and tissue be maintained. Stern et al clearly teach that the electrode may be provided either within the balloon member, or on the balloon member. Stern et al further teach of providing a conductive fluid or gel through a porous inflatable member, similar to the concept of Phan et al. As such, the examiner maintains that one of ordinary skill in the art would find ample suggestion to provide the electrode member either within the balloon, or on the balloon surface in view of the

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Stern et al disclosure of providing a conductive fluid through a porous member to a tissue surface. With regard to the cooling structure of Phan et al, the examiner maintains that an electrode on the external surface of the balloon would still be cooled by a cooling fluid passing through the balloon member and would function in much the same capacity. That Phan et al has selected an internal electrode in the design of the device does not explicitly preclude the use of other design choices, and providing an electrode on the outer surface would not destroy the functionality of the Phan et al device in any way.

To further support the examiner's position, attention is also directed to the Edwards et al (5,505,730) device which also discloses a porous balloon member having a flow of conductive cooling fluid into the balloon, and electrodes that may be either within the balloon structure, or on the surface of the balloon structure. The examiner maintains that the art of record clearly demonstrates the alternative placement of an electrode either on the surface or within a porous balloon member for the treatment of tissue, and that one of ordinary skill in the art would be properly motivated to provide such an alternative electrode placement in the Phan et al device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner
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/mp/
September 4, 2007